# SAM'S TOWN

HOTEL, GAMBLING HALL AND BOWLING CENTER JAN 27 A11:07

LOCATED ON THE BOULDER STRIP • FLAMINGO & BOULDER HIGHWAY

TO:

Dockets Mgmt Branch (HFA-305)

Food and Drug Administration

5600 Fishers Lane Rockville, MD 20857

FROM:

Ronald L. Van Diest

DATE:

January 14, 2000

SUBJECT:

Laser Variance

Request expeditious handling of the attached request as the previous variance expired on June 17, 1998.

SAM'S TOWN HOTEL AND GAMBLING HALL

RONALD L. VAN DIEST

ASSISTANT FACILITY MANAGER 702-454-8032

P.O. Box 12001 5111 Boulder Highway Las Vegas, Nevada 89122-5089 702-456-7777 702-454-8021 Fax 800-697-8696 Administrative 800-634-6371 Reservations A BOYD GAMING CORPORATION

Call me with any comments or questions you may have concerning this matter.

Ronald L Van Diest

Ass't Facility Manager

941-0204

EXPI

5111 Boulder Highway • Las Vegas, NV 89122 • (702) 456-7777
Toll Free Numbers: Canada, United States & Nevada
Reservations
1-800-634-6371
Administrative Office
1-800-897-8696

## DEPARATMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND CRUG ADMINISTRATION

## APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE

	Lypratum Pater August 11, 1988
	DOCKET NUMBER
.	9.437-0.204

application in accordance with 21 CFR 1010.4.  1. Check all applicable boxes and type or print the requested	INSTRUCTIONS  3. Mail your application is the Drug Administration, Room	Dockets Management Branch (HFA-305), Food and a 4-62, 5600 Fishers Lane, Rockville, MD 20857.				
information. 2. Submit an original and four (4) copies.	4. Enter Document Number if					
NAME OF COMPANY		a til og til ett er er forste statt fræker stil grundstaten forste forste kollege skale forste som er er Forste forste forste skale til state forste skale forste forste forste kollege skale forste som er er er er b				
SAM'S TOWN HOTEL AND CASING	o de la financia de la compressión del compressión de la compressi					
ADDRESS OF COMPANY (Include ZIP CODE) (If P.O. Bux is used, include	uction street address also.)					
5111 S. Boulder Highway, La	as Vegas Nevada 89122	2				
NAME AND TITLE OF RESPONSIBLE PERSON	4. TELEPHONE NO. (Include area code)	5. DATE OF SUBMISSION				
ONALD L. VANDIEST ASS'T Fac Mg		1/14/2000				
The applicant requests the variance to be in effect for a period of	years from the date of issue. rind is remusted, a matification must be uttoched as pur	of the upplication.)				
	ODUCT DESCRIPTION AND USE	and provided the control of the provided meeting of the provided and the control of the control of the control				
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SUNSET STAMPEDE" LASER SHOW_US	WITH I ARGON LASER AI	IV IMAGE ENGINEERING MODI ND 2 KRYPTON LASERS				
b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED		D BE USED AT ANY ONE LOCATION				
A LASER DISPLAY DEVICE	MORE THAN 15 DAYS	S OT MORE THAN 15 DAYS				
A PROJECTOR FOR A LASER LIGHT SHOW	LESS THAN 5 DAYS	WINDERSTAND WATE				
☐ OTHER (Species)						
	g. TOUR IS INTENDED TO RU					
c. PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO LASER LIGHT SHOW PRODUCERS		HS				
d. PRODUCT IS INTENDED FOR USE IN A	LESS THAN I MONTH					
PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE	□ NOT APPLICABLE (m)	the first of the second of the first of the second of the				
THEATER	OTHER (Specify)					
MOOR DNITEEM RO MOORLIAG JETOMILETOH	e se uitre de la companya de la comp	**************************************				
STORE DISPLAYS	_	h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS  XX FRONT SCREEN PROJECTIONS				
TRADE SHOW OR CONVENTION	REAR SCREEN PROJ					
U DISCOTHEQUE OR NIGHT CLUB	HOLOGRAPHIC DISF	The state of the s				
PAVILION INDOOR ARENA	XX MULTIPLE REFLECT	CNIDIFFRACTION EFFECTS				
OUTDOOR ARENA	AUDIENCE SCANNIN	G (Also includes scarring any accessible incontrolled areas.)				
MUSEUM		STATIONARY MIPPORS OR MIRRORED SURFACES				
OUTDOOR UNENCLOSED AREA	(Rean Matrices.)	ATION OF ROTATING MIRROR BALLS, ETC.				
TY OTHER (Special) ATRIUM, ENCLOSED		TION OF ROTATING MIRROR BALLS, ETC.				
e. PRODUCT IS INTENDED TO BE USED	XX FIBER OPTIC PROJECT					
AT ONLY ONE (FILM) LOCATION	XX FOG. SMOKE, OR OT	XX FOG. SMOKE. OR OTHER SCATTERING ENHANCEMENT EFFECTS				
AT A VARIETY OF (Inne) LOCATIONS	OTHER (Speech)	· <del></del>				
OTHER (Specify)	1. 11 Aces					
	LASER RADIATION LEVELS	entre i destrucció de magni cambane. La compositació de las selectores de la compositore de la compositore de l Contractores				
LASER MEDIUM (Ac. He-Ne. etc.)	WAVE LENGTHS (nm)	PEAK POWER /IEury				
Argon - Coherent Innova						
400-20 laser system	0.514 um	11.4 W				
2-Krypton - Coherent	1 Company of the Comp					
200K3 series laser	0.647	5.9 W				
and the second s		en e				
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IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE	DURATION AND RATE AND SCANNING FREQUE	NCY AND AMPLITUDE THAT I THAT I THE SAME THE SAM				
N/A						
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XX COMPLIANCE WITH THE LIMITS OF 21 CFR 1040.17(d) WOULD RE	STRICT THE INTENDED USE OF THE PRODUCT 3	ECAUSE COMPLIANCE WOULD LIMIT THE OUTPUT				
POWER TO THE EXTENT THAT THE DESIRED EFFECTS WOULD N	OT BE SUFFICIENTLY VISIBLE	rent er en				
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11.	XX	MANNER IN WHICH IT IS PROPOSED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARD  XX IT IS PROPOSED TO DEVIATE FROM THE PROVISIONS OF 21 CFR 1040.11(c) IN THAT THE ACCESSIBLE EMISSION LEVEL WOULD EXCEED THE ACCESSIBLE EMISSION LIMITS SPECIFIED IN 21 CFR 1040.11(c).  IT IS PROPOSED TO DEVIATE FROM THE PROVISION OF 21 CFR 1040.11(c) AS FOLLOWS:							
		70	1 Common						
12	AOV	/AN	TAGES TO BE DERIVED FROM SUCH DEVIATION						
	XX	LA:	SER LIGHT SHOWS AND DISPLAYS ARE ACCEPTED POPULAR MEDIA IN ENTERTAINMENT AND THE ARTS. USE OF POWER LEVELS IN CESS OF THE LIMITS IMPOSED BY 21 CFR 1040.11(c) IS NECESSARY TO ACHIEVE THE REQUIRED EFFECTS IN THESE MEDIA.  HER OR ADDITIONAL ADVANTAGES (describe and explain)						
13.	EXP	الكيا	N THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. (Check as many boxes as apply. In item 14 "Remarks," justify any boxes						
	not c	c/mc	ked, using additional sheets as necesssary. State any other means of radiation protection that will be used.)						
	a.	Ă	ALL LASER PRODUCTS, SYSTEMS, SHOWS, AND PROJECTORS WILL BE CERTIFIED TO COMPLY WITH 21 CFR 1040.10 AND THE CONDITIONS OF THIS VARIANCE AND WILL BE REPORTED AS REQUIRED BY 21 CFR 1002.10 AND 1002.12 USING THE REPORTING GUIDES PROVIDED FOR SUCH PURPOSE. THESE ACTIONS WILL BE ACCOMPLISHED PRIOR TO ANY INTRODUCTION INTO COMMERCE.						
	b.	X	EFFECTS NOT SPECIFICALLY INDICATED IN THIS VARIANCE APPLICATION WILL NOT BE PERFORMED. NO OTHER EFFECTS WILL BE ADDED UNTIL AN AMENDMENT TO THE VARIANCE HAS BEEN OBTAINED AND THE REQUIRED REPORTS OR SUPPLEMENTS, AS APPLICABLE, HAVE BEEN SUBMITTED.						
	c.	¥	SCANNING. PROJECTION. OR REFLECTION OF LASER AND COLLATERAL HADIATION (LIGHT SHOW RADIATION) INTO AUDIENCE OR OTHER ACCESSIBLE UNCONTROLLED AREAS WILL NOT BE PERMITTED EXCEPT FOR DIFFUSE REFLECTIONS PRODUCED BY THE ATMOSPHERE, ADDED ATMOSPHERIC SCATTERING MEDIA, AND TARGET SCREENS.						
	d.	豆	LASER RADIATION LEVELS IN EXCESS OF THE LIMITS OF CLASS I WILL NOT BE PERMITTED AT ANY POINT LESS THAN 3.0 METERS ABOVE ANY SURFACE UPON WHICH PERSONS OTHER THAN OPERATORS, PERFORMERS, OR EMPLOYEES ARE PERMITTED TO STAND OR 2.5 METERS BELOW OR IN LATERAL SEPARATION FROM ANY PLACE WHERE SUCH PERSONS ARE PERMITTED TO BE, OPERATORS, PERFORMERS, AND EMPLOYEES WILL NOT BE REQUIRED OR ALLOWED TO VIEW RADIATION ABOVE THE LIMITS OF CLASS I OR BE EXPOSED TO RADIATION ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c).						
	e.	<b>S</b>	ANY PRODUCT WHICH RELIES ON SCANNING TO MEET ACCESS, EXPOSURE, OR PRODUCT CLASS LIMITS WILL INCORPORATE A SCANNING SAFEGUARD SYSTEM WHICH DIRECTLY SENSES SCANNER MOTION AND WHICH WILL REACT FAST ENOUGH TO PRECLUDE EXCEEDING THE APPLICABLE LIMIT.						
	f.	×	ALL LASER LIGHT SHOWS SHALL BE UNDER THE DIRECT AND PERSONAL CONTROL OF TRAINED, COMPETENT OPERATOR(S). THE OPERATOR(S) WILL:						
5			(1) IMMEDIATELY TERMINATE THE EMMISSION OF LIGHT SHOW RADIATION IN THE EVENT OF ANY UNSAFE CONDITION;						
			(2) BE LOCATED WHERE ALL BEAM PATHS CAN BE DIRECTLY OBSERVED AT ALL TIMES; AND						
			(3) BE AN EMPLOYEE OF THE VARIANCE HOLDER WHO WILL BE RESPONSIBLE FOR THE TRAINING AND CONDUCT OF THE OPERATOR.						
	g.	X	THE MAXIMUM LASER PROJECTOR OUTPUT POWER WILL NOT EXCEED THE LEVEL REQUIRED TO OBTAIN THE INTENDED EFFECTS.						
	n.	Ø	THE PROJECTION SYSTEM (I.E., THE PROJECTOR AND ALL OTHER COMPONENTS USED TO PRODUCE THE LIGHTING EFFECTS) WILL BE SECURELY MOUNTED OR IMMOBILIZED TO PREVENT UNINTENDED MOVEMENT OR MISALIGNMENT. BEAM LIMITERS WILL BE PROVIDED AS AN INHERENT PART OF THE SYSTEM DESIGN TO PREVENT OVERFILLING OF SCREENS, BEAM STOPS, TARGETS, ETC.						
	i.	Ø	LASER PROJECTORS WILL NOT BE DELIVERED TO ANY OTHER PARTY UNDER AN AGREEMENT OF SALE, LEASE, OR LOAN UNLESS AND UNTIL THE RECIPIENT DEMONSTRATES THAT THEY HAVE A VARIANCE IN EFFECT AT THE TIME OF DELIVERY THAT PERMITS THEM TO PRODUCE LASER LIGHT SHOWS INCORPORATING SUCH PROJECTOR.						
	J		IN ADDITION TO THE REQUIREMENTS OF 21 CFR 1040.10(h), THE MANUFACTURER OF LASER PROJECTORS/SYSTEMS WILL PROVIDE TO PARTIES WHO PURCHASE, LEASE, OR BORROW THE EQUIPMENT, ADEQUATE USER'S INSTRUCTIONS FOR SAFE INSTALLATION AND OPERATION AND WHICH EXPLAIN THE RESPONSIBILITY OF THE RECIPIENT AS AN INDEPENDENT LIGHT SHOW MANUFACTURER TO SUBMIT THE REQUIRED REPORTS AND APPLY FOR AND OBTAIN A VARIANCE FROM CORN PRIOR TO INTRODUCTION INTO COMMERCE OF ANY LASER LIGHT SHOWS.						
			THE REQUIREMENTS OF 21 CFR 1002.30(a)(1) AND (2) WILL BE ACCOMPLISHED THROUGH THE USE OF WRITTEN PROCEDURES FOR SETUP, ALIGNMENT, TESTING, AND PERFORMANCE OF EACH SHOW. THESE PROCEDURES WILL BE IN SUFFICIENT DETAIL TO ENSURE COMPLIANCE WITH 21 CFR 1040.10. THE CONDITIONS OF THIS VARIANCE, AND THE CONTROL OF ACCESS TO RADIATION AREAS USING THE PROCEDURES DESCRIBED IN THE ANSI 2136.1 STANDARD FOR THE SAFE USE OF LASERS (AMERICAN NATIONAL STANDARDS INSTITUTE, 1430 BROADWAY, NEW YORK, NY 10018) OR ANY OTHER EQUIVALENT USER CONSENSUS STANDARD AND, WHERE APPLICABLE, STATE OR LOCAL REQUIREMENTS. LASER RADIATION AREAS WHICH CAN CONTAIN RADIATION LEVELS ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c), WILL BE CLEARLY IDENTIFIED BY THE POSTING OF WARNING SIGNS AND/OR RESTRICTING ACCESS THROUGH PHYSICAL MEANS (SUCH AS PRESSURE SWITCHES, PHOTOCELLS, BARRIERS, GUARDS, ETC.), THESE REQUIREMENTS APPLY TO TEMPORARY AREAS (SUCH AS OURING SET-UP AND ALIGNMENT PROCEDURES) AND TO FINAL OR PERMANENT AREAS. THE VARIANCE HOLDER WILL RETAIN THE RECORDS OF THESE PROCEDURES AND THE RESULTS OF ALL TESTS AS REQUIRED BY 21 CFR 1002.31, A COPY OF THE VARIANCE APPLICATION. THE APPROVAL LETTER, CURRENT PROCEDURES, AND RECORDS RELATING TO EACH PARTICULAR SHOW WILL SE WITH THE OPERATOR OR OTHER RESPONSIBLE INDIVIDUAL AND WILL BE MADE AVAILABLE FOR INSPECTION BY FDA AND OTHER RESPONSI-						
	in the second of	e Jane mener	BLE AUTHORITIES.						

ADVANCE WRITTEN NOTIFICATION WILL BE MADE AS EARLY AS POSSIBLE TO APPROPRIATE FEDERAL STATE, AND LOCAL AUTHORITIES PROVIDING SHOW ITINERARY WITH DATES AND LOCATIONS CLEARLY AND COMPLETELY IDENTIFIED. AND A BASIC DESCRIPTION OF PROPOSED EFFECTS INCLUDING A STATEMENT OF THE MAXIMUM POWER OUTPUT INTENDED. SUCH NOTIFICATIONS WILL BE MADE, BUT NOT NECESSARILY BE LIMITED, TO: (1) THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, OFFICE OF COMPLIANCE (HFZ312), 8757 GEORGIA AVE. SILVER SPRING, MO 20910, PROVIDING THE INITIAL AND CLOSING DATES FOR FIXED INSTALLATIONS AND THE ITINERARY FOR MOBILE SHOWS. IN ADDI-TION, UNLESS ALL ASPECTS OF EACH SHOW HAVE BEEN REPORTED AND THE ACCESSION NUMBERS CLEARLY REFERENCED, EACH NOTICE WILL INCLUDE DETAILED DESCRIPTIONS OF EACH SHOW AND A LISTING OF ALL EFFECTS TO BE PERFORMED IN SUFFICIENT DETAIL TO CONFIRM COMPLIANCE WITH THE REGULATIONS AND THIS VARIANCE. (2) THE FEDERAL AVIATION ADMINISTRATION (FAA) FOR ANY PROJECTIONS INTO OPEN AIRSPACE AT ANY TIME (I.E., INCLUDING SET-UP, ALIGNMENT, REHEARSALS, PERFORMANCES, ETC.). IF THE FAA OBJECTS TO ANY LASER EFFECTS, THE OBJECTIONS WILL BE RE-SOLVED AND ANY CONDITIONS REQUESTED BY FAA WILL BE ADHERED TO. IF THESE CONDITIONS CAN NOT BE MET, THE OBJEC-TIONABLE EFFECTS WILL BE DELETED FROM THE SHOW. (3) STATE AND LOCAL RADIATION CONTROL OFFICES/AGENCIES FOR ALL SHOWS TO BE PERFORMED WITHIN THEIR JURISDICTIONS. ALL REQUIREMENTS OF STATE AND LOCAL LAW WILL BE SATISFIED AND ANY OBJECTIONS RAISED BY LOCAL AUTHORITIES WILL BE REsolved or the effects deleted. (Lists of Federal and State Offices are available from the center for devices and RADIOLOGICAL HEALTH UPON REQUEST.) REMARKS Not a manufacturer of laser projectors or systems. Equipments will not be sold, leased or lent to other users. 13 J -

CERTIFICATION

I CERTIFY that all of the above information and statements are true, complete, and correct to the best of my knowledge and acknowledge that my variance application may be denied or my variance may be revoked if this application is found to be false, misleading, or incorrect in any material way. I have submitted and will submit all reports required by 21 CFR 1002.10 and 1002.12 on the laser equipment and shows). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE

16. NAME (Type or Print)

RONAD L. VAN DIEST

17. TITLE

Assistant Facility Mgr

### DEPARATMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION

## APPLICATION FOR A VARIANCE FROM 21 CFR 1040.11(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE

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.pratrii	Date:	Insu-i	₩.	1482	

94V-0204

OTE: No laser light show, projection system, or device may	vary from compliance with 21 CFR 1040	.11(c) in design or use without the approval of this
application in accordance with 21 CFR 1010.4.		
The second secon	INSTRUCTIONS	
1. Check all applicable boxes and type or print the requested	3. Mail your application to	the Dockets Management Branch (HFA-305), Food and
information.	Drug Administration, Re 4. Enter Document Number	iom 4-62, 5600 Fishers Lane, Rockville, MD 20857.
2. Submit an original and four (4) copies.	4. Enter Doctainent Number	entrate and the destruction of the second se
1. NAME OF COMPANY		The second secon
SAM'S TOWN HOTEL AND CASIN		
ADDRESS OF COMPANY (Inclinie ZIP CODE) (If P.O. Bus is used, inclinia	uring street wildress also.)	wakasa waka basan akke akasa a 190 ku alian kata ya 190 ku a 190 k
4 .5-4	as Vegas Nevada 891	22
5111 S. Boulder Highway. 1	4. TELEPHONE NO. (Include area code)	5. DATE OF SUBMISSION
		1/14/2000
RONALD L. VANDIEST ASS'T Fac Mc	r 1 702 454-8032	1 1/14/2000
o. The applicant requests the variance to be in effect for a period of 2 (In general, the Agency will approve a variance for only two years, If a longer p	years from the date of issue. weight is requested, a postilization must be utilizabet as i	part of the application.)
	RODUCT DESCRIPTION AND USE	
	the state of the s	
a. LIST NAME ANDIOR MODEL NUMBERIS FOR THE LASER LIGHT SH	OW(S) AND PROJECTOR(S)	TV IMAGE ENGINEERING MODE
"SUNSET STAMPEDE" LASER SHOW US SERIES 3700T PROJECTION SYSTEM	ING CERTIFIED CLASS WITH I ARGON LASER	AND 2 KRYPTON LASERS
b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED	f. PRODUCT IS INTENDED	TO BE USED AT ANY ONE LOCATION
	XX MORE THAN 15 DA	
A LASER DISPLAY DEVICE		T NOT MORE THAN 15 DAYS
A PROJECTOR FOR A LASER LIGHT SHOW	LESS THAN 5 DAY	
A LASER LIGHT SHOW		·
OTHER (Specify)	g. TOUR IS INTENDED TO	RUN FOR
G. PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO	O OTHER XX MORE THAN 6 MO	NTHS
laser light show producers	_ 1-6 MONTHS	
d. PRODUCT IS INTENDED FOR USE IN A	LESS THAN 1 MON	VTH
PLANETARIUM OR OTHER DOME PROJECTION STRUCTURE	☐ NOT APPLICABLE	(and a time)
THEATER	OTHER (Specify)	
HOTELMOTEL BALLROOM OR MEETING ROOM		
STORE DISPLAYS	h, PRODUCT UTILIZES THE	E FOULOWING LASER EFFECTS
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	REAR SCREEN PR	OJECTIONS
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	XX MULTIPLE REFLEC	CTION/DIFFRACTION EFFECTS
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MUSEUM	(Beam Matrices.)	
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X OTHER (Specific ATRIUM, ENCLOSED	SCANNING IRRAD	HATION OF ROTATING MIRROR BALLS, ETC.
e. PRODUCT IS INTENDED TO BE USED	XX FIBER OPTIC PRO	JECTIONS
AT ONLY ONE WILLIAM LOCATION	XX FOG. SMOKE, OR	OTHER SCATTERING ENHANCEMENT EFFECTS
AT A VARIETY OF (1001) LOCATIONS	OTHER (Specify)	
OTHER (Specify)		
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LASER MEDIUM (Ar. He-Ne. etc.)	WAVE LENGTHS (nm)	PEAK POWER /III/II/
Argon - Coherent Innova		<u> </u>
	0 514 nm	11.4 W
400-20 laser system		The state of the s
2-Krypton - Coherent		5.9 W
200K3 series laser	0.647	5.9 W
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OTHER OR ADDITIONAL EXPLANATION (Species)		
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			And the second s
12.	AD	VAN	TAGES TO BE DERIVED FROM SUCH DEVIATION
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13.	not	(J) 1990	N THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED. (Check as many boxes as apply. In Item 14 "Remarks," justify any boxes ked, using additional sheets as necessary. State any other means of radiation protection that will be used.)
	a.	X	ALL LASER PRODUCTS, SYSTEMS, SHOWS, AND PROJECTORS WILL BE CERTIFIED TO COMPLY WITH 21 CFR 1040.10 AND THE CONDITIONS OF THIS VARIANCE AND WILL BE REPORTED AS REQUIRED BY 21 CFR 1002.10 AND 1002.12 USING THE REPORTING GUIDES PROVIDED FOR SUCH PURPOSE. THESE ACTIONS WILL BE ACCOMPLISHED PRIOR TO ANY INTRODUCTION INTO COMMERCE.
	b.	X	EFFECTS NOT SPECIFICALLY INDICATED IN THIS VARIANCE APPLICATION WILL NOT BE PERFORMED. NO OTHER EFFECTS WILL BE ADDED UNTIL AN AMENDMENT TO THE VARIANCE HAS BEEN OBTAINED AND THE REQUIRED REPORTS OR SUPPLEMENTS, AS APPLICABLE, HAVE BEEN SUBMITTED.
	c.	*	SCANNING, PROJECTION, OR REFLECTION OF LASER AND COLLATERAL RADIATION (LIGHT SHOW RADIATION) INTO AUDIENCE OR OTHER ACCESSIBLE UNCONTROLLED AREAS WILL NOT BE PERMITTED EXCEPT FOR DIFFUSE REFLECTIONS PRODUCED BY THE ATMOSPHERE, ADDED ATMOSPHERIC SCATTERING MEDIA, AND TARGET SCREENS.
reru. )	<b>d.</b>	显	LASER RADIATION LEVELS IN EXCESS OF THE LIMITS OF CLASS I WILL NOT BE PERMITTED AT ANY POINT LESS THAN 3.0 METERS ABOVE ANY SURFACE UPON WHICH PERSONS OTHER THAN OPERATORS, PERFORMERS. OR EMPLOYEES ARE PERMITTED TO STAND OR 2.5 METERS BELOW OR IN LATERAL SEPARATION FROM ANY PLACE WHERE SUCH PERSONS ARE PERMITTED TO BE. OPERATORS. PERFORMERS, AND EMPLOYEES WILL NOT BE REQUIRED OR ALLOWED TO VIEW RADIATION ABOVE THE LIMITS OF CLASS I OR BE EXPOSED TO RADIATION ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c).
	ę.	X	ANY PRODUCT WHICH RELIES ON SCANNING TO MEET ACCESS. EXPOSURE, OR PRODUCT CLASS LIMITS WILL INCORPORATE A SCANNING SAFEGUARD SYSTEM WHICH DIRECTLY SENSES SCANNER MOTION AND WHICH WILL REACT FAST ENOUGH TO PRECLUDE EXCEEDING THE APPLICABLE LIMIT.
	4. 5.	7	ALL LASER LIGHT SHOWS SHALL BE UNDER THE DIRECT AND PERSONAL CONTROL OF TRAINED COMPETENT OPERATORIS), THE OPERATORIS WILL:
			(1) IMMEDIATELY TERMINATE THE EMMISSION OF LIGHT SHOW RADIATION IN THE EVENT OF ANY UNSAFE CONDITION:
			(2) BE LOCATED WHERE ALL BEAM PATHS CAN BE DIRECTLY OBSERVED AT ALL TIMES: AND
			(3) BE AN EMPLOYEE OF THE VARIANCE HOLDER WHO WILL BE RESPONSIBLE FOR THE TRAINING AND CONDUCT OF THE OPERATOR.
	g.	Ø	THE MAXIMUM LASER PROJECTOR OUTPUT POWER WILL NOT EXCEED THE LEVEL REQUIRED TO OBTAIN THE INTENDED EFFECTS.
	'n.		THE PROJECTION SYSTEM (I.E., THE PROJECTOR AND ALL OTHER COMPONENTS USED TO PRODUCE THE LIGHTING EFFECTS) WILL BE SECURELY MOUNTED OR IMMOBILIZED TO PREVENT UNINTENDED MOVEMENT OR MISALIGNMENT. BEAM LIMITERS WILL BE PROVIDED AS AN INHERENT PART OF THE SYSTEM DESIGN TO PREVENT OVERFILLING OF SCREENS, BEAM STOPS, TARGETS, ETC.
	i.	£	LASER PROJECTORS WILL NOT BE DELIVERED TO ANY OTHER PARTY UNDER AN AGREEMENT OF SALE, LEASE, OR LOAN UNLESS AND UNTIL THE RECIPIENT DEMONSTRATES THAT THEY HAVE A VARIANCE IN EFFECT AT THE TIME OF DELIVERY THAT PERMITS THEM TO PRODUCE LASER LIGHT SHOWS INCORPORATING SUCH PROJECTOR.
	i-		IN ADDITION TO THE REQUIREMENTS OF 21 CFR 1040.10(h), THE MANUFACTURER OF LASER PROJECTORS/SYSTEMS WILL PROVIDE TO PARTIES WHO PURCHASE, LEASE, OR BORROW THE EQUIPMENT, ADEQUATE USER'S INSTRUCTIONS FOR SAFE INSTALLATION AND OPERATION AND WHICH EXPLAIN THE RESPONSIBILITY OF THE RECIPIENT AS AN INDEPENDENT LIGHT SHOW MANUFACTURER TO SUBMIT THE REQUIRED REPORTS AND APPLY FOR AND OBTAIN A VARIANCE FROM CORN PRIOR TO INTRODUCTION INTO COMMERCE OF ANY LASER LIGHT SHOWS.
	<b>k.</b>		THE REQUIREMENTS OF 21 CFR 1002.30(a)(1) AND (2) WILL BE ACCOMPLISHED THROUGH THE USE OF WRITTEN PROCEDURES FOR SETUP, ALIGNMENT, TESTING. AND PERFORMANCE OF EACH SHOW. THESE PROCEDURES WILL BE IN SUFFICIENT DETAIL TO ENSURE COMPLIANCE WITH 21 CFR 1040.10, THE CONDITIONS OF THIS VARIANCE, AND THE CONTROL OF ACCESS TO RADIATION AREAS USING THE PROCEDURES DESCRIBED IN THE ANSI ZI36.1 STANDARD FOR THE SAFE USE OF LASERS (AMERICAN NATIONAL STANDARDS INSTITUTE, 1430 BROADWAY. NEW YORK, NY 10018) OR ANY OTHER EQUIVALENT USER CONSENSUS STANDARD AND, WHERE APPLICABLE, STATE OR LOCAL REQUIREMENTS, LASER RADIATION AREAS WHICH CAN CONTAIN RADIATION LEVELS ABOVE THE LIMITS SPECIFIED IN 21 CFR 1040.11(c), WILL BE CLEARLY IDENTIFIED BY THE POSTING OF WARNING SIGNS AND/OR RESTRICTING ACCESS THROUGH PHYSICAL MEANS (SUCH AS PRESSURE SWITCHES, PHOTOCELLS, BARRIERS, GUARDS, ETC.), THESE REQUIREMENTS APPLY TO TEMPORARY AREAS SUCH AS DURING SETUP AND ALIGNMENT PROCEDURES) AND TO FINAL OR PERMANENT AREAS. THE VARIANCE HOLDER WILL RETAIN THE RECORDS OF THESE PROCEDURES AND THE RESULTS OF ALL TESTS AS REQUIRED BY 21 CFR 1002.31, A COPY OF THE VARIANCE APPLICATION. THE APPROVAL LETTER, CURRENT PROCEDURES, AND RECORDS RELATING TO EACH PARTICULAR SHOW WILL SE WITH THE OPERATOR OR OTHER RESPONSIBLE INDIVIDUAL AND WILL SE MADE AVAILABLE FOR INSPECTION BY FDA AND OTHER RESPONSIBLE AUTHORITIES.

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RONAD L. VAN DIEST

17. TITLE

Assistant Facility Mgr



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